DHHS Public Records

From: Meyer, Diana
Sent: Friday, September 22, 2017 3:43 PM
To: steve.karlen@40daysforlife.com
Cc: DHHS Public Records
Subject: Survey/Inspection Reports Requested
Attachments: Lincoln PP and Survey Report-PUBLIC.pdf; BHC APPROVD POC PUBLIC.pdf; Omaha PP Approved POC.pdf; Bellevue - Bellevue Health Center RV Ltr.pdf; Omaha - Planned Parenthood of the Heartland RV Ltr.pdf; Lincoln - Planned Parenthood of the Heartland RV Ltr.pdf

Categories: FILE

Mr. Karlen,
Per your request, attached you will find the survey/inspection reports for the following facilities since January 1, 2015 :

Bellevue Health Center – Bellevue (they have only had 1 inspection on 8/6/2015 with a follow up inspection on October 21, 2015)
Planned Parenthood of the Heartland – Lincoln (they have only had 1 inspection on 8/20/2015 with a follow up inspection on July 5, 2016)
Planned Parenthood of the Heartland – Omaha (they have only had 1 inspection on 8/21/2012 with a follow up inspection on

Diana Meyer | *DHHS Program Manager II*
PUBLIC HEALTH
Nebraska Department of Health and Human Services

From: Steven Karlen [mailto:steve.karlen@40daysforlife.com]
Sent: Thursday, September 21, 2017 3:09 PM
To: DHHS Acute Care Facilities <DHHS.AcuteCareFacilities@nebraska.gov>
Subject: RE: Survey/Inspection Reports

Thank you so very much!

Would it be possible to see those for the clinics I referenced for 2015-present?

Thank you again.

Steve Karlen
Director, North American Campaigns
40 Days for Life
608-445-2063

From: DHHS Acute Care Facilities [mailto:DHHS.AcuteCareFacilities@nebraska.gov]
Sent: Thursday, September 21, 2017 2:52 PM
To: 'steve.karlen@40daysforlife.com' <steve.karlen@40daysforlife.com>
Subject: FW: Survey/Inspection Reports

Mr. Karlen,
We received your email below. We do not currently post survey/inspection information on the License Details site for any facilities other than long term care facilities at this time. We are slowly transitioning to doing that, but haven't gotten there yet.
Survey records are public information, however, so if you would like the copies of the survey reports for any licensed facility type, please let me know the dates that you would like these reports for. For example, you can say the 'past year' or you can say 'any report in 2017'. And I will be more than glad to provide them to you.
Sincerely,

Diana Meyer | *DHHS Program Manager II*
PUBLIC HEALTH
Nebraska Department of Health and Human Services

From: Steven Karlen [mailto:steve.karlen@40daysforlife.com]
Sent: Wednesday, September 20, 2017 2:25 PM
To: DHHS Health Care Facilities <DHHS.HealthCareFacilities@nebraska.gov>
Subject: Survey/Inspection Reports

Greetings,

I am trying to retrieve facility information as well as the survey/inspection reports for the Bellevue Health Center (1002 West Mission, Bellevue) as well as Planned Parenthood in both Omaha (3105 North 93rd Street) and Lincoln (5631 South 48th Street, Suite 100).

I have visited Nebraska.gov and found the "License Details" for all three locations. However, though news accounts have referenced inspections of the Bellevue Health Center, "Nothing on record at this time" appears in both the "facility information" and "Survey/Inspection Information."

Please advise. Thank you!

Steve Karlen
Director, North American Campaigns
40 Days for Life
608-445-2063

Department of Health & Human Services
DHHS
NEBRASKA

Division of Public Health

State of Nebraska
Pete Ricketts, Governor

August 26, 2015

Jennifer Warren-Ulrick
Administrator
Planned Parenthood of The Heartland
5631 South 48th Street, Suite 100
Lincoln, NE 68516

CERTIFIED MAIL

Dear Ms. Warren-Ulrick:

The enclosed report documents a finding of noncompliance with the licensure regulations for Health Clinics prepared following the focus survey that was conducted at your facility and completed on August 20, 2015 by Sharon Wellensiek, Registered Nurse, and Mary Kulhanek, Registered Dietician/Licensed Medical Nutrition Therapist, surveyors with the Nebraska Department of Health and Human Services Division of Public Health.

The violations found must be corrected within 90 days to avoid disciplinary action against the facility's license. Therefore, a written statement of compliance must be submitted to the Department within 10 working days of receipt of this letter. The statement of compliance must include the following:

1) How the corrective action will be accomplished for individuals found to have been affected by the violation;
2) What measures will be put into place for systemic changes made to ensure that the violation will not recur and how potential to affect others will be identified;
3) How the facility will monitor its corrective actions/performance to ensure that the violation is being corrected and will not recur, i.e. what program will be put into place to monitor the continued effectiveness of the systemic change to ensure that solutions are permanent;
4) Identify person(s) by position, not individual name, who will be responsible for monitoring and ensuring that compliance is achieved and continues;
5) A realistic date by which each violation will be corrected; and
6) Signature of the administrator or other authorized official and date.

If you fail to submit and implement a statement of compliance, the Department may initiate disciplinary action against the facility license.

If you have any questions regarding this correspondence, contact this office.

Sincerely,

Diana Meyer, RN BSN - Program Manager
Office of Acute Care Facilities
DHHS Public Health - Licensure Unit
PO Box 94986, Lincoln, NE 68509-4986
(402) 471-3484 FAX (402) 742-8319
Email: diana.meyer@nebraska.gov

DM/smm

Enclosures: State Form
Survey Evaluation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HC059	A. BUILDING: _____ B. WING _____	08/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF THE HEARTLANI	5631 SOUTH 48TH STREET, SUITE 100 LINCOLN, NE 68516

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
G 020	7-006.01 Licensure Responsibilities The licensee of each health clinic must assume the responsibility for the total operation of the facility. The licensee responsibilities include: 1. Monitoring policies to assure the appropriate administration and management of the health clinic; 2. Maintaining the health clinic ' s compliance with all applicable state statutes and relevant rules and regulations; 3. Providing quality care and treatment to patients whether care and treatment are furnished by health clinic staff or through a contract with the health clinic; 4. Periodically reviewing reports and recommendations regarding the Quality Assurance/Performance Improvement program and implementing programs and policies to maintain and improve the quality of patient care and treatment; 5. Maintaining written minutes of meetings and actions; 6. Designating an administrator who is responsible for the day to day management of the health clinic and defining the duties and responsibilities of the administrator in writing; 7. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be responsible for the position until another administrator is appointed; 8. Notifying the Department in writing within five working days when the vacancy is filled including effective date and name of person appointed administrator; and 9. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the health clinic.	G 020		

Licensure Unit

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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G 020	Continued From page 1 This Standard is not met as evidenced by: Surveyor: 04557 Based on staff interview and review of policy and procedures, the health clinic (HC) failed to complete and/or submit the required Report of Induced Abortion form to the Nebraska Department of Health and Human Services (NDHHS) within 15 days after the reporting month for five months out of seven months since January 1, 2015. Nebraska State Statute 28-343 requires the following "The Department of Health and Human Services shall prescribe an abortion reporting form which shall be used for the reporting of every abortion performed in this state....The completed form shall be signed by the attending physician and sent to the department within fifteen days after each reporting month." Findings are: A. A review of the facility policy and procedure 'Statistical Reporting' (revised June 2015), revealed the following: "The State of Nebraska requires that all abortions performed in the state be reported within 15 days of the end of the calendar month in which the abortion was performed. Nebraska Department of Health and Human Services has provided us with a form to utilize for this purpose. The form is called Report of Induced Abortions. One form is filled out for each patient who has an abortion or spontaneous termination of pregnancy. The PP Heartland [Planned Parenthood] clinician who performed the abortion must sign the form. Forms are mailed monthly to the Vital Records Office by the 15th of the month."	G 020		

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G 020	Continued From page 2 B. Interview with Center Assistant - A by telephone on 8/19/15 from 2:53 PM to 3:05 PM and again on 8/20/15 from 9:00 AM to 9:05 AM revealed the following: -The Center Assistant "started completing the Report of Induced Abortions in March or April when another employee left"; -The Center Assistant has completed 2 monthly reports and "gave the first month to the Assistant Manager to mail and the second month to the Center Manager to mail"; and -July reports have not been completed yet. Surveyor: 21534 C. A review of DHHS statistical data revealed the following information regarding the facility reporting: January 2015 - Report due to DHHS by February 15, 2015; the facility report was received on March 4, 2015. February 2015 - Report due to DHHS by March 15, 2015; the facility report was received on March 23, 2015. March 2015 - Report due to DHHS by April 15, 2015; the facility report was received on April 13, 2015. April 2015 - Report due to DHHS by May 15, 2015; the facility report was received on May 19, 2015. May 2015 - Report due to DHHS by June 15, 2015; the facility report was received on June 8, 2015. June 2015 - Report due to DHHS by July 15, 2015; the facility report was received on August 6, 2015.	G 020		

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G 020	Continued From page 3 July 2015 - Report due to DHHS by August 15, 2015. As of August 25, 2015, no report had been received.	G 020		

Nebraska DHHS Licensure Unit

SEP 22 2015

RECEIVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HC001	A. BUILDING: _____ B. WING _____	C 08/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BELLEVUE HEALTH CENTER	1002 WEST MISSION BELLEVUE, NE 68005

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
G 150	7-006.06 Patient Care and Treatment Each health clinic must establish and implement written policies and procedures that encompass all care and treatment provided to patients. The policies and procedures are consistent with prevailing professional standards, delineate the scope of services provided in the health clinic and encompass aspects to protect the health and safety of patients. This Standard is not met as evidenced by: Based on observation, staff interview and policy review; the facility failed to have a policy in place to consistently identify tissue specimen(s) removed during the abortion procedure (extraction of fetal tissue from the uterus) that were stored in the freezer. Five of Five specimens in the freezer were not consistently identified. This procedure had the potential to effect any tissue specimen(s) stored by the facility. Findings are: A. During the facility tour on 8/4/15 from 12:00 PM to 1: 20 PM; the freezer (which had been identified for storage of tissue specimens) was observed to have five tissue specimen(s) with the following identification: -Specimen 1-- A tissue specimen wrapped in a chux (a water impermeable pad) placed in a plastic bag identified with initials and a date written with a magic marker; -Specimen 2-- A tissue specimen wrapped in a chux placed in a plastic bag identified with a first initial, last name and a patient number written with a magic marker; -Specimen 3-- A tissue specimen wrapped in a chux placed in a plastic bag identified with the words 'room 1 specimen' and the date written	G 150	**G 150 7-006.06 A.** **Specimen 1-5 were all disposed of in red biohazard bags and in biohazard box in garage.** **The DON will be responsible for Checking the freezer monthly.**	08/04/15

Licensure Unit

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: M L Carhart

TITLE: Clinic Administrator

(X6) DATE: 09/18/2015

Nebraska DHHS Licensure Unit

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G 150	Continued From page 1 with a magic marker; - Specimen 4-- A tissue specimen wrapped in a chux placed in a plastic bag identified with a first name, last name and the date written with a magic marker; and - Specimen 5 -- A tissue specimen wrapped in a chux placed in a plastic bag without any identifying information such as a name, number or date written on the bag. B. An interview with the Director of Nurses [DON] during the tour on 8/4/15 from 12:00 PM to 1:20 PM revealed, that there needed to be a better system for identification of the specimens in the freezer. The DON identified that there was not a specific policy or procedure in place for labeling and identifying specimens placed in freezer for hold. C. Per a written response as part of the physician interview dated 8/13/15, the sole exception to the disposal of tissue via protocol for the certified medical waste disposal company pick up would be: "a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study. b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence. c) A request from the patient to have the tissue released to a licensed funeral director or a agent to prepare the fetus for cremation or burial." D. Review of the facility Policy and Procedure Manual, Section 8 -Procedure Manual: Identification of Products of Conception (POC) revealed the following information: "...If the POC was a result of rape, it will be put in sterile specimen cup, labeled and placed in the	G 150	**G 150 7-006.06 B-D** **The policy for Products of Conception has been updated.** **See Attachments 1-3** **G 150 7-006.06 D** **Amendment to Dr. Carhart's Response.** **See Attachment 24**	08/07/15

Nebraska DHHS Licensure Unit

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BELLEVUE HEALTH CENTER	1002 WEST MISSION BELLEVUE, NE 68005

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
G 150	Continued From page 2 freezer." The Policy and Procedure Manual lacked any further protocol regarding the identification and management of frozen tissue specimens.	G 150		
G 410	7-006.09E Storage of Drugs/Devices/Biologicals All drugs, devices, and biologicals must be stored in secured areas and stored in accordance with the manufacturer ' s, distributor ' s, packager ' s, or dispensing pharmacist ' s instructions for temperature, light, humidity, and other storage instructions. Only authorized personnel, designated by policy and procedure of the health clinic as responsible for administration, provision, or dispensing, must have access to drugs, devices, and biologicals. The supply of drugs, devices, and biologicals must be protected and restricted to use for legally authorized purposes and must be checked on a regular basis to ensure expired, mislabeled, unlabeled, or unusable products are not available for patient use. This Standard is not met as evidenced by: Based on observation and staff interview; the facility failed to ensure that expired biologicals were not available for patient use. Two of Two exam room cupboards contained boxes of Lamicel Osmotic Cervical Dilators and Laminaria Tents [a thin rod of dried kelp that is placed into the cervix (the "neck" of the uterus) to soften and dilate (open) the cervix prior to the abortion procedure (extraction of fetal tissue from the uterus)]. [Each box contained 20-24 Cervical Dilators in individualized pouches.] This had the potential to effect all patients requiring the use of this product for an abortion procedure.	G 410		

Nebraska DHHS Licensure Unit

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G 410	Continued From page 3 Findings are: A. Observations made on the facility tour 8/14/15 from 12:00 PM to 1:20 PM revealed the following: 1) Exam Room 1 had a cupboard that contained multiple boxes of Lamicel Osmotic Cervical Dilators and Laminaria Tents. The following boxes of Laminaria/Lamicel Osmotic Cervical Dilators were outdated: -5 boxes of 4 mm (millimeter long) / 70 mm (millimeter diameter) Laminaria Tents which were outdated 9/2014 and 1 box that was outdated 11/2013; -1 box of 2 mm / extra small Laminaria Tents with an outdate of 1/2014 and 1 box that outdated 7/2015; -1 box of 6 mm / 70 mm Laminaria Tents with an outdate of 12/2011; 4 boxes that outdated 7/2014; and 1 box that outdated 7/2015; -1 box of 3 mm / (no other mm listing on box related to diameter) of Lamicel Osmotic Cervical Dilators with an outdate of 8/2005; 1 box with an outdate of 10/2005; 1 box with an outdate of 5/2008 and 1 box with an outdate of 7/2008; and -2 boxes of 5 mm / (no other mm listing on box related to diameter) of Lamicel Osmotic Cervical Dilators with an outdate of 7/2008 and 1 box outdated 12/2003. 2) Exam Room 2 had a cupboard that contained multiple boxes of Laminaria Tent. The following boxes of Laminaria were outdated: -1 boxes of 4 mm (millimeter long) / 70 mm (millimeter diameter) Laminaria Tents with an outdate of 11/2013; -1 box of 2 mm / extra small Laminaria Tents with an outdate of 3/2014; and -1 box of 8 mm / 70 mm Laminaria Tents with an	G 410	**G 410 7-006.09E A1-2** **All expired supplies were disposed of properly.** **The DON will check for expiration dates monthly**	08/04/15

Nebraska DHHS Licensure Unit

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G 410	Continued From page 4 outdate of 2/2015. B. Staff interview (during the tour on 8/4/15 from 12:00 PM to 1:20 PM) with the Director of Nurses for the clinic revealed, "I do monthly checks to check for expired medications, but didn't realize that those had outdated."	G 410	**G 410 7-006.09E** **New policies written for supplies.** **See Attachments 4-5**	08/07/15
G 530	7-006.15B Equipment, Fixtures, and Furnishings The facility must provide and maintain all equipment, fixtures, and furnishings clean, safe and in good repair. 7-006.15B1 The facility must establish and implement a process designed for routine and preventative maintenance of equipment and furnishings to ensure that such equipment and furnishings are safe and function to meet the intended use. This Standard is not met as evidenced by: Based on observation and staff interview; the facility failed to: 1)establish preventative maintenance processes for 7 of 10 sampled pieces of medical equipment (2 ultrasound machines - medical equipment that uses sound waves to produce images of what is going on inside the body; 2 defibrillator/cardiac monitors - used only for monitoring the rhythm of the heart; 1 cautery machine - an instrument used to cut and repair tissue; 2 suction machines - a machine which has a tube that provides suction to removed tissue or fluid from the body) and 2) implement preventative maintenance for 3 of 10 sampled pieces of medical equipment (3 autoclaves - a machine that sterilizes medical instruments in between patient use). This failed practice has the potential to affect all patients receiving surgical procedures at the clinic.	G 530		

Nebraska DHHS Licensure Unit

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G 530	Continued From page 5 Findings are: A. A tour of the clinic on 8/4/15 from 12:00 PM to 1:20 PM; revealed the following medical equipment with no evidence of preventive maintenance on the equipment: -Procedure Room 1 - ultrasound machine, defibrillator/cardiac monitor, suction machine, and cautery machine; -Procedure Room 2 - ultrasound machine, defibrillator/cardiac monitor, and suction machine. Interview with the Director or Nursing (DON) on 8/4/15 from 12:00 PM to 1:20 PM (during the tour) indicated that no one provided preventive maintenance on the above equipment. B. A tour of the clinic on 8/4/15 from 12:00 PM to 1:20 PM; revealed 3 autoclaves in the center sterilization room. The DON provided a 3-ring note book that contained log sheets titled '2015 Autoclave' for each autoclave machine. The log sheets contained an area for documenting completion of weekly, monthly and Maxi Test maintenance (a test that is completed to make sure the sterilizer is working properly). The following directions were listed at the bottom of the log sheets: "Please initial and date when completed." The log sheet for each of the 3 autoclaves only contained initials on the weekly log for January 2015. All other areas on the form were blank. C. Interview with the DON on 8/6/15 from 9:50 AM to 10:10 AM revealed that the clinic lacked a policy and procedure for preventive maintenance on equipment. Interview with the Clinic Manager 8/6/15 from 11:15 AM to 11:45 AM revealed that the clinic had no scheduled preventive	G 530	**G 530 7-006. 15B A-C** All machines have been maintenance according to Owner Manuals that have been located online or through the manufacturer. New policies written for Machine Maintenance. The DON will check the logs monthly. See Attachments 6-23	08/24/15 08/24/15

Nebraska DHHS Licensure Unit

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G 530	Continued From page 6 maintenance for the medical equipment.	G 530		

Procedure Manual: Medical Abortion Using Mifeprex.

Purpose: To ensure that all patients coming into our clinic receive the safest procedure possible.

- After education is complete, make a copy of the signed Mifeprex Guide.
- The copy will be sent home with the patient.
- Collect medications for the patient.
- Get the desired birth control ready for the patient.
- Rhogam needs to be given.
- Get a glass of water for the patient to take Mifeprex.
- Notify the Physician that the patient is ready to be seen.
- The patient needs to stay in the clinic 30 minutes after taking the pill.
- The patient needs to schedule the 2 week follow-up before leaving the clinic.
- Patient should be logged in the Medical Follow-up book.
- If the patient does not return for the required 2 week follow-up, staff will need to contact them by phone. If staff is unsuccessful in reaching the patient 3 times, a letter will be mailed to the address given to the clinic by the patient.
- If the patient fails to reply, they will then be marked as "Non-Compliant" in the system and will not be allowed to choose the Medical procedure if returning to the clinic.
- Patients that return for the 2 week follow-up will be checked in and an ultrasound will be done to ensure the pregnancy tissue was evacuated from the uterus.

Procedure Manual: Identification of Products of Conception

Purpose: To ensure that the Products of Conception (POC) is complete for the gestation of the patients undergoing abortion before the patient leaves the clinic.

- After the abortion, the tissue will be rinsed and placed in a glass dish over the backlight.
- The Physician or a staff member trained to identify the POC will check all tissue for completeness. Results will be charted on the back of the patients chart in the appropriate area.
- Products of Conception under 10 weeks of gestation will have a photo taken. The picture number will be charted on the patient's chart.
- All tissue will then be placed in ziplock bag with Wavicide. This ziplock of tissue will be collected at the end of the day and placed in a red biohazard bag that will be put in the pickup container provided by the company assigned to dispose of our biohazard waste.
- POC's will be put in biohazard waste in the garage and Picked up by GRP.
- Any tissue that is questionable will be brought to the Physician's attention. The Physician will then determine if tissue and/or blood should be saved.

- Patients with questionable tissue will be instructed on ectopic precautions and may be given Methotrexate with the Physician's orders. Instructions and/or methotrexate given will be charted on the patients chart.
- If the POC was a result of rape, it will be put in sterile specimen cup, labeled and placed in the freezer for gestations under 12 weeks. 13 weeks and up place specimen in clean chuck.
- If a patient has opted to have the POC cremated, this may done at the patient's expense and needs to be approved before procedure begins.
- POC's that are frozen will be put in biohazard waste after 6 months.
- POC form will be filled out and put in patient chart.
- POC's will be clearly labeled with the patient's chart number. FI's can also be labeled with first initial and last name along with chart number.

Procedure Manual: Gestations under 6 weeks

Purpose: To ensure the procedure was successful.

- Any patient with a gestation below 6 weeks, must fill out Under Six Week consent form.
- These patients must agree to return to our clinic for follow-up. If the patient does not agree, they will not be seen.
- These patients will be logged as a Mandatory Follow-Up in the specimen book. If they do not return for a 4 week follow-up, we will attempt to be contacted by phone three times. If this is unsuccessful, a letter will be mailed to the address provided by the patient.

Procedure Manual: Possible Ectopic Pregnancy Protocol

Purpose: To ensure that all potential patients with an ectopic pregnancy are treated appropriately.

- Any patient with an empty uterus on ultrasound and a positive pregnancy test and any patient with a positive pregnancy test and ultrasound confirming a pregnancy that yields tissue unsatisfactory to confirm completion will be annotated in the "Mandatory Follow up Log" as a potential ectopic pregnancy. At the discretion of the physician the patient may be administered methotrexate at the dose of 50 mg / meter square or as directed.
- Each patient that falls into this category will be instructed, and their record annotated, that they must return in at least 48 hours but less than 14 days, or immediately for severe cramping or bleeding of greater than two pads per hour, for two hours.
- If an ectopic pregnancy is seen on ultrasound to accompany an intrauterine pregnancy (approx. 1/35,000 risk) the intrauterine pregnancy is to be terminated and the patient immediately transferred to the hospital of her choice.
- If the ectopic pregnancy does not have an intrauterine twin the patient is to be immediately referred for definitive treatment.

Attachment
2

AbortionClinics.Org 1002 West M. .on Ave, Bellevue, NE 68005 402-291-47. ax: 402-291-4643

Products of Conception

Patient Name_____ DOB_____

POC labeled_____ Date_____

Reason for keeping tissue_____

_____

_____

If POC is leaving the building, who is it being released to_____

Date Released_____ By_____

Signature of Recipient_____

If POC is returned to the building, place POC in biohazard waste bag and put in garage.

Date Returned_____ By_____

Signature of Staff that Received POC_____

Please attach any receipts and/or orders received.

Attachment 3

POC LOG

Date POC Put in Freezer	POC Labeled	Form in Chart	Remove By Date	Removed On	By

Procedure Manual: Environmental Safety

Purpose: To ensure the clinic is maintained in a manner that minimizes accidents.

- Keep surfaces smooth and free of sharp edges, mold, or dirt; keeping floors free of objects and slippery or uneven surfaces and keeping the environment free of other conditions which may pose a potential risk.
- Maintain all doors, stairways, passageways, aisles, or other means of exit in a manner that provides safe and adequate access for care and treatment.
- Provide water for bathing and handwashing at safe and comfortable temperatures to protect patients from potential for burns or scalds.
- Monitor and maintain water temperatures that accommodate comfort and preferences but not to exceed the following temperatures:
    - Water temperature at patient handwashing fixtures must not exceed 120 degrees Fahrenheit.

Procedure Manual: Hazardous/Poisonous Materials

Purpose: To ensure hazardous/poisonous materials are handled, stored and disposed of properly.

- All hazardous/poisonous materials will be kept in locked cabinets
- Gloves should be worn when handling these materials to prevent damage to skin
- hazardous/poisonous materials will be disposed of as suggested by MSDS
- Spill kits will be kept in close proximity of hazardous/poisonous materials
- Any biohazard materials will be put in red bags and put in biohazard trash in the garage

Procedure Manual: Management of Supplies

Purpose: To ensure the clinics supplies are stored, stocked and dated properly

One staff member will be assigned the task of ordering, organizing and keeping the supplies the clinic needs to operate.

This person will also be responsible for checking supplies for expiration dates and separating expired stock from good stock.

Expired stock will be disposed of properly.

Procedure Manual: Management of Laminaria Stock

Purpose: To ensure that laminaria are logged and not expired

When laminaria are received in the clinic, they should be logged with date received, type of laminaria, quantity, lot # and expiration date. All new stock should be put away in Room 1. The stock will be checked weekly when staff checks for expired instruments.

Procedure Manual: Instrument care

Purpose: To ensure that all instruments used in the facility are cleaned and/or sterilized properly.

- All instruments will be placed in a 10% bleach solution after use. The instruments will remain in solution for 10 minutes. Make sure all instruments are completely covered with the bleach solution before setting the timer.
- When the timer goes off the instruments will be taken out of the 10% bleach solution and placed in the sink.
- The sink will be filled with water and 1 oz of Alconox powder.
- All instruments will then be thoroughly scrubbed and rinsed.
- Instruments will then be placed on a towel to dry.
- After drying, the metal instruments will be placed in sterilization pouches and sealed with the sterilization tape.
- Using a permanent marker the name of the instrument, date, expiration date (6 months from current date), and the initials of the staff member will be written on the tape.
- All pouches will then be placed in the sterilizer.
- **Exceptions:** All speculums and 1st day tennaculums will be cleaned as above and without wrapping will placed directly in the autoclave.
- Sterilization will be at 270 degrees F for 20 min. at 27psi.
- Cannulas will be tossed and replaced with fresh, sterile cannulas after each use.

All suction tubing and bottles will be cleaned as above and then left to dry. These can be re-used immediately after cleaning. These do not need to be autoclaved.

Attachment 5

Laminaria Log

Date Received	Laminaria Brand	Size	Qty	Lot #	Expiration Date	Received By	Removed Date

Procedure Manual: Equipment Maintenance

Purpose: To ensure all of our equipment is maintained and logged according to the manufacture.

Ultrasounds:

Mindray Z-6 Maintenance

All functions of this device may be used. Maintenance should be as follows.

- Probes should be cleaned after every use
- Check the surface of the probe daily
- Clean display monthly
- Clean trackball monthly
- Clean control panel monthly
- Clean probe cable and the surface of connector monthly
- Clean all holders monthly
- Clean cover monthly
- Clean peripherals monthly
- Check power cable and plug monthly
- Check battery annually
- Check function of peripherals and options annually
- Mechanical safety inspection annually
- Electrical safety inspection every 2 years by authorized Mindray technician

The maintenance will be logged in the Machine Maintenance book located the in scrub room.

Shimadzu Ultrasound Maintenance

This machine is only used for simultaneous viewing during the procedure. This ultrasound will not be used to determine gestation.
The following maintenance will be performed monthly.

- External Cleaning
- Inspect power cord

EKG:

Burdick Medic 4 Maintenance

This device will ONLY be used as a cardiac monitor. The defibrillator capabilities will NEVER be used. The AED will be used in case of emergency.
Preventive Maintenance should be performed at least once per year. We will do these steps monthly.

- Visually inspect the defibrillator
- Clean the defibrillator
- Check the power cord
- Check the patient cable
- Inspect the printhead

The maintenance will be logged in the Machine Maintenance book located the in scrub room.

Electrocautery:

Birthcher 771-2 Maintenance
This device is used only for Vasectomy patients and setup is done by physician. Little maintenance is required for this machine. The following maintenance will be performed monthly.

- External Cleaning
- Inspect power cord

Oximeters:

Autocorr Maintenance
This device does not require any maintenance. The following maintenance will be performed monthly.

- Clean all external surfaces
- Inspect finger probe
- Inspect power cord

Burdick Oxy 100 Maintenance
This device does not require any maintenance. The following maintenance will be performed monthly.

- Clean all external surfaces
- Inspect finger probe
- Inspect power cord

Thermometers:

Welch Allyn SureTemp Plus Maintenance

- Check batteries
- Clean all external surfaces
- Remove/clean probe well

Mabis Maintenance

- Check batteries
- Clean all external surfaces

Hemoglobin

Hemopoint H2 Maintenance (see maintenance book)

- Disconnect power
- Housing and touch screen
- Microcuvette holder
- Optical unit
- Power adapter

Autoclaves

M11 UltraClave Steam Sterilizer Maintenance

The following maintenance procedures are to be performed.

Daily (patient days only):

- Clean external surfaces
- Clean Sterilizer Door Gasket

Weekly (patient weeks only):

- Drain reservoir
- Fill with new distilled water
- Clean chamber and Trays

Monthly Flush the System:

- Drain reservoir
- Fill with new distilled water
- Add 1 ounce of speed clean sterilizer to a cool chamber
- Run 30 minute cycle (packs) with no instruments
- Drain reservoir
- Fill with new distilled water
- Run 3 minute cycle (unwrapped)
- Drain reservoir and allow to cool to room temperature
- Remove trays and tray rack
- Wipe out the inside of the chamber, trays and rack
- Re-install the tray rack and trays
- Refill with new distilled water

Monthly Cleaning Chamber Filter:

- Before performing this procedure, make sure that the sterilizer has cooled to room temperature
- Remove all trays, tray rack, and tray plate from the chamber
- Locate the chamber filter on the bottom of the chamber
- Grasp filter and gently pull upwards while twisting slightly
- Clean the filter with mild soap and distilled water
- Rinse with distilled water
- Replace the filter

Monthly Maxi-Test

Monthly Pressure Relief Valve Check

- Remove the top inspection cover
- Select the unwrapped cycle and start the cycle
- When the "heat up" protion of the cycle is complete and the elapsed time is being counted down on the display panel, pull upward on wire ring of pressure relief valve with a screwdriver for approximately 3 seconds: steam should discharge freely from beneath the rear of the unit
- Release the wire ring
- Press stop to prevent the unit from overheating
- Install top inspection cover

Quarterly:

Remove and Clean Door Gasket:

- Remove dam gasket and door gasket from door
- Clean the gaskets with a mild detergent and inspect for cracks, cuts, shrinkage, or swelling.
- Clean gasket housing channel with mild soap and distilled water
- Press the door gasket into the channel then install dam gasket
- Run one cycle to seat the gaskets properly

Suction:

Synevac System 10 Maintenance:

The Synevac System is designed to make clean-up and maintenance quick and easy. There are no required maintenance checks for the vacuum pump and the unit requires no oil.

Daily Set-up (Patient Days Only):

- Attach tubing and bottles to the machine
- Use your finger to close off system.
- Turn on vacuum
- Document the maximum number displayed on vacuum gauge on daily flow log

Daily Cleaning (Patient Days Only):

- Prompt removal of spills will protect the cabinet finish. Use soap and water.
- Disconnect the tubing and remove the glass collection bottles. Soak tubing, rubber top and bottles in 10% bleach solution for 10 minutes and then wash with Alconox and water and allow to dry after each patient. The back bottle must be soaked at the end of the day unless contents from front bottle overflowed to the back bottle.
- Wipe down all surfaces of the machine with sani-wipe after each patient
- Replace rubber o rings and gaskets when they show signs of wear to insure consistent vacuum levels
- Check the disposable filter. If discolored, remove the filter and replace it with a new one
- Remove the overflow safety jar and ball float. Clean the parts with soap and water and let them dry

Monthly Visual Inspection

- Check all hoses for vacuum leaks.
- Check all hose connections into and out of the collection bottles and the disposable filter assembly.
- Check all gaskets and o rings. They must be fitted properly to insure a good seal.
- Check that the overflow jar is properly screwed into place.

Annual Functional Inspection

- Check the pump by removing the hose connected to the pump inlet fitting. Cover the fitting with your finger. Check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose.
- Remove the interconnecting hose from the disposable filter. Cover the metal female fitting on the interconnecting hose and check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose.
- Remove the interconnecting hose from the second bottle assembly. Cover the metal inlet port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the hose.
- Remove the collection set tubing to check the first collection bottle assembly and the interconnecting (bottle to bottle) hose. Cover the female metal port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the collection set.
- Cover the end of your collection set tubing. Check the gauge.

*If there is a leak in the system that you cannot locate, call for service.

Mindray Z-6 Maintenance

Date of purchased: 05/22/2014 Began Use: June 2014

2020

Clean the probes after every use. See Ultrasound policy
Daily Maintenance- Check surface of probe. See Ultrasound policy

Maintain Content	Frequency	Method	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean Display	Monthly	9.2.1												
Clean trackball	Monthly	9.2.1												
Clean control panel	Monthly	9.2.1												
Clean probes	Every use	9.2.1												
Clean probe cable and the surface of connctor	Monthly	9.2.1												
Clean all holders	Monthly	9.2.1												
Clean cover	Monthly	9.2.1												
Clean peripherals	Monthly	9.2.2												
Check surface of probe	Daily	9.3.1												
Check power cable and plug	Monthly	9.3.1												
Check battery	Annually	9.3.1												
Check function of Peripherals and options	Annually	9.3.3												
Mechanical safety inspection	Annually	9.3.4												
Electrical safety inspection	2 years	Service	Authorized Mindray Technician Only **Due June of even years											

Attachment 7

Maintenance Log Shimadzu 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Shimadzu 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Shimadzu 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Shimadzu 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Attachment 8

Maintenance Log Medic 4 (room 1) 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Medic 4 (room 1) 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Medic 4 (room 1) 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Maintenance Log Medic 4 (room 1) 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Visually inspect the defibrillator												
Clean the defibrillator												
Check the power cord												
Check the patient cable												
Inspect the printhead												

Attachment 9

Maintenance Log Birtcher 771-2 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Birtcher 771-2 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Birtcher 771-2 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Maintenance Log Birtcher 771-2 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Dry all surfaces												
Inspect power cord												

Attachment 10

Maintenance Log Oximeter 2015

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2016

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2017

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Maintenance Log Oximeter 2018

Autocorr AH07010114

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Inspect power cord												

Attachment 11

Maintenance Log Oximeter 2015

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Oximeter 2016

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Oximeter 2017

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Maintenance Log Oximeter 2018

Burdick Oxy 100

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Clean all external surfaces												
Inspect finger probe												
Check batteries												

Attachment 12

Maintenance Log Welch Allyn SureTemp Plus 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Welch Allyn SureTemp Plus 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Welch Allyn SureTemp Plus 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Welch Allyn SureTemp Plus 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												
Remove/clean probe well												

Maintenance Log Mabis Thermometer 2015

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Mabis Thermometer 2016

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Mabis Thermometer 2017

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Maintenance Log Mabis Thermometer 2018

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check batteries												
Clean all external surface												

Attachment 14

Maintenance Log Hemopoint H2 2015

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Maintenance Log Hemopoint H2 2016

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Maintenance Log Hemopoint H2 2017

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Maintenance Log Hemopoint H2 2018

*Disconnect power

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Housing and touchscreen												
Microcuvette holder												
Optical unit												
Power adapter												

Monthly Visual Inspection

2016 **SV-10 #4568**

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check all hoses for vacuum leaks												
Check all hose connections into and out of the collection bottles and the disposable filter assembly												
Check all gaskets and o rings												
Check that the overflow jar is properly screwed into place												

Annual Functional Inspection

Check the pump by removing the hose connected to the pump inlet fitting. Cover the fitting with your finger Check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the disposable filter. Cover the metal female fitting on the interconnecting hose and check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the second bottle assembly. Cover the metal inlet port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the hose	
Remove the collection set tubing to check the first collection bottle assembly and the interconnecting (bottle to bottle) hose. Cover the female metal port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the collection set	
Cover the end of your collection set tubing. Check the gauge	

Attachment 16

Monthly Visual Inspection

2016 **SV-10 #4226**

	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Check all hoses for vacuum leaks												
Check all hose connections into and out of the collection bottles and the disposable filter assembly												
Check all gaskets and o rings												
Check that the overflow jar is properly screwed into place												

Annual Functional Inspection

Check the pump by removing the hose connected to the pump inlet fitting. Cover the fitting with your finger Check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the disposable filter. Cover the metal female fitting on the interconnecting hose and check the gauge. If the reading is normal (60 or above), reattach the interconnecting hose	
Remove the interconnecting hose from the second bottle assembly. Cover the metal inlet port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the hose	
Remove the collection set tubing to check the first collection bottle assembly and the interconnecting (bottle to bottle) hose. Cover the female metal port of the bottle top with your finger. Check the gauge. If the reading is normal (60 or above), reconnect the collection set	
Cover the end of your collection set tubing. Check the gauge	

Attachment 17

Daily Vacuum Flow Checks 2015 SV-10 #4568

	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
6												
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Attachment 18

Daily Vacuum Flow Checks 2016 SV-10 #4226

	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
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Attachment 19

Daily Autoclave Cleaning Log

2015

V641964

Day	January	February	March	April	May	June	July	August	September	October	November	December
1												
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Attachment 20

Daily Autoclave Cleaning Log 2015 ES-004740

Day	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												
6												
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Attachment 21

Weekly Log — 2015 — V-641964

Week	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												

Monthly Flush Log

January	February	March	April	May	June	July	August	September	October	November	December

Monthly Filter Log

January	February	March	April	May	June	July	August	September	October	November	December

Quarterly Log

January		April		July		October	

Maxi Test

January	February	March	April	May	June	July	August	September	October	November	December

****Please initial and date when completed. Thanks!****

Monthly Pressure Relief Log

***Supervisor to complete**

January	February	March	April	May	June	July	August	September	October	November	December

Attachment 22

Weekly Log — 2015 — ES-004740

Week	January	February	March	April	May	June	July	August	September	October	November	December
1												
2												
3												
4												
5												

Monthly Flush Log

January	February	March	April	May	June	July	August	September	October	November	December

Monthly Filter Log

January	February	March	April	May	June	July	August	September	October	November	December

Quarterly Log

January		April		July		October	

Maxi Test

January	February	March	April	May	June	July	August	September	October	November	December

****Please initial and date when completed. Thanks!****

Monthly Pressure Relief Log

***Supervisor to complete**

January	February	March	April	May	June	July	August	September	October	November	December

Attachment 23

LeRoy H Carhart, MD
1002 W. Mission Ave.
Bellevue, NE 68005

September 16, 2015

Nebraska DHHS Licensure Unit;

1. On August 13, 2015, I submitted my answers to Nebraska DHHS, to: "**Questions from DHHS Nebraska submitted on August 6, 2015, To Dr. LeRoy Carhart with responses.**"

2. A copy of the answers is attached.

3. When I was reviewing our responses on Nebraska DHHS Licensure Unit: Summary of Deficiencies," State Form 3UQ11, I realized that I had made a serious omission in my response to question 1. The answer as submitted is:

"... The sole exceptions to this policy occurs when we have:

a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study.
b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence.
c) A request from the patient to have the tissue released to a licensed funeral director or his agent to prepare the fetus for cremation or burial.

4. The answer should have a new paragraph "c)" and paragraph "c)" needs to become paragraph "d)". The correct answer and the amendment needed to my response, changes underlined, should read:

"... The sole exceptions to this policy occurs when we have:

a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study.
b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence.
c) <u>A request from the patient, a legal guardian, a reporting authority or the attending physician to have the tissue saved so that should the authorities desire the specimen it will be available.</u>
d) A request from the patient to have the tissue released to a licensed funeral director or his agent to prepare the fetus for cremation or burial.

Respectfully submitted:

LeRoy H Carhart, MD

Attachment 1: Questions from DHHS Nebraska submitted on August 6, 2015, To Dr. LeRoy Carhart with responses, dated August 13, 2015.

LeRoy H Carhart, MD
1002 W. Mission Ave.
Bellevue, NE 68005

August 13, 2015

**Questions from DHHS Nebraska submitted on August 6, 2015,
To Dr. LeRoy Carhart with responses.**

2. What happens to the medical waste/fetal tissue after the procedure/abortion?

In accord with standard practices used in similar practice settings, in vacuum aspiration abortions, the tissue travels through a closed system into a collection jar containing a 10% bleach solution. At the end of the procedure the tissue and solution is filtered through a strainer to remove fetal tissue. Then the decontaminated tissue is then "floated" in tap water to identify the adequacy of fetal parts, to help determine that the abortion is complete. Following examination the tissue is put into a container containing "wavicide". At the end of the day or when the container is full, it is placed in a "hazardous waste" container to await pick-up from a certified medical waste disposal company. The sole exceptions to this policy occurs when we have:

a) A request from a referring provider to have the tissue forwarded to a laboratory for further diagnostic study.
b) A request from a law enforcement agency or jurisdiction to have the tissue surrendered to an agent for evidence.
c) A request from the patient to have the tissue released to a licensed funeral director or his agent to prepare the fetus for cremation or burial.

In accord with standard practices used in similar practice settings in each of these scenarios the tissue is prepared to meet the requirements of the agency concerned.

In accord with standard practices used in similar practice settings with second trimester (dilatation and evacuation) abortions the tissues are removed by forceps and vacuum aspiration. The vacuum aspirated portion is treated as above. The tissue removed by forceps is also submerged in the solution and floated for identification. It is also then placed in wavicide and placed in the "hazardous" waste container as described above.

3. Where is the medical waste tissue stored?

In accord with standard practices used in similar practice settings fetal tissue or products of conception are stored in red bagged "hazardous" waste containers in separate sealed pouches. The tissue is immersed in

wavicide. These containers are kept in our indoor garage area separated from the clinic by firewalls. The area is separately locked from the clinic.

4. How does the facility remove the medical waste?

MedPro Disposal is our agent to dispose of our medical waste. All containers and liners are supplied by the licensed carrier. A copy of our contract is attached as attachment 1. I have also attached as attachment 2, a copy of the receipt for our last pick up. As the "hazardous" waste containers become filled they are sealed. Once a month they are picked up by the licensed medical waste disposal company, MedPro Disposal. This is in accord with standard practices used in similar practice settings

5. Who all has access to the area where the medical waste is stored?

All staff members have access to the locked area. Current staff members are:

i. LeRoy H Carhart, M.D., Medical Director
ii. Mary Lou Carhart, Clinic Administrator
iii. Lindsey R Koch (Creekmore), R.N. Director of Nursing
iv. Melissa Hill, Medical Assistant
v. Ashley Edwards, Medical Assistant
vi. Shavon Meadows, Medical Assistant

6. Are individual fetal waste/specimens transported to any other facilities?

No fetal tissue has been transported to any other facility since we stopped donating tissue to the University of Nebraska. The last time occurred in the early 2000's.

7. Explain the role(s) of ultrasound used at the clinic i.e. prior to procedure and during the procedure?

Ultrasound's role is described in SOGC Guideline #303. A copy is furnished and incorporated into my answer as attachment 3. The role of the ultrasound at this facility is to aid in the determination of the gestational age of the fetus and to aid in the safety of the performance and the completion of the abortion.

8. What training do staff completing the ultrasound receive?

I have attached as Attachment #1. Our ultrasound training protocol.

9. How is their competency evaluated?

Every ultrasound is evaluated by me prior to the start of the abortion. I then use "real-time" ultrasound during the entire abortion procedure. I am

able to compare what the staff members sonogram shows with what I see in the operating room. All discrepancies and findings of note are reviewed on the spot with the technician that did the original sonogram. All measurements and placement are reviewed with the technician thus assuring that technician training and competency are evaluated daily.

10. Are pictures of the ultrasound printed off or is there a report printed off?

For 1st trimester abortions when only a single structure is measured only the picture with the measurements are printed. For 2nd trimester abortions or when multiple structures are measured, both the pictures and the reports are printed. The "Ultrasound Training Annual Review Form" is completed annually for each employee. The form is included as attachment 3.

11. How is gestational age determined?

A part of my answer to question ten appears in response to question 11 below. See that response. However, I am aware of the SOGC Clinical Practice Guidelines, and specifically Guideline # 303 published in February 2014 entitled "Determination of Gestational Age by Ultrasound". As is observed in the Abstract Summary Statement; "When performed with quality and precision, ultrasound alone is more accurate than a "certain" menstrual date for determining gestational age in the 1st and 2nd trimesters in spontaneous conceptions, and it is the best method for estimating the delivery date." I attempt to adhere to the SOGC Guideline.

12. What are the guidelines for weeks of gestation? (Particularly 20 weeks and over) i.e. which procedure is used?

A part of my answer to question eleven appears in response to question 10 above. See that response.

It is common in most obstetrical circles in the United States to define gestation age using the pregnancy start date as the first day of the mother's last normal menstrual cycle (LNMP). Thus when a woman misses her first menstrual cycle she is said to be four weeks pregnant.

The State of Nebraska has chosen to use the actual date of conception as the first day of the pregnancy. Thus on the day of the first missed menstrual cycle the woman is said to have a gestation age of two weeks.

Establishing a patient's gestation is best done using clinical judgement. This should take into account all available parameters to include history, physical exam, ultrasound and other test results that may add to the thought process.

13. Have you been approached in regards to the purchase of fetal tissue?

I have never been approached to sell tissue at any of my practice locations.

From time to time groups that collect tissue for scientific reasons have attended medical meetings and continuing education programs that I have also attended. I do not know whether it is accurate to say that I have been approached, but I have told at least one of these groups at some time past not expressly recalled that my protocols and the state law, as I understand it, preclude my donation of fetal tissue.

As I am well aware of both the law and ethics involved I have never even considered a sale of said tissues.

Respectfully submitted:

LeRoy H Carhart, MD

Attachment 1: Contract with MedPro Disposal
2: Last Invoice from MedPro Disposal with receipt
3: SOGC Guideline #303 "Determination of Gestational Age by Ultrasound"
4: Ultrasound Policy
5: Ultrasound Training Form
6: Ultrasound Training Annual Review Form

Meyer, Diana

From: Warren-Ulrick, Jennifer <Jennifer.Warren-Ulrick@PPHeartland.org>
Sent: Tuesday, September 15, 2015 2:03 PM
To: Meyer, Diana
Cc: Moeller, Suzette; McQuinn, Kim; Racey, Lindsay
Subject: RE: PP plan of correction letter

Hi Diana,

Sorry I forgot that piece! The Nebraska health centers will be fully compliant by 10/15/15.

Please let me know if there is anything else.

Thanks!

POC approved. 9/16/15 dlm/sw

Jennifer Warren Ulrick
Director of Health Services
Planned Parenthood of the Heartland

jwu

From: Meyer, Diana [mailto:Diana.Meyer@nebraska.gov]
Sent: Monday, September 14, 2015 1:33 PM
To: Warren-Ulrick, Jennifer
Cc: Moeller, Suzette; McQuinn, Kim
Subject: PP plan of correction letter
Importance: High

Jennifer,

Thank you for submitting your plan of corrective action for the inspections conducted at the Lincoln and Omaha Planned Parenthood health clinics. We appreciate your timeliness! We do still need a date from you as to when you expect the facilities to be in correction. This needs to be a specific date sometime from the date of the exit until whenever you felt/feel they will be corrected. , i.e, October 1, 2015, etc.

If you have any questions, please give me a call. Thanks again!

Diana Meyer, RN, BSN – Program Manager
Acute Care Facilities/CLIA/Healthcare Facility Construction
301 Centennial Mall, S, 3rd Floor
Lincoln, NE 68508
402-471-3484
diana.meyer@nebraska.gov
DHHS.facilityconstruction@nebraska.gov
DHHS. acutecarefacilities@nebraska.gov

dlm 9/15/15

Planned Parenthood
Care. No matter what.

Planned Parenthood of the Heartland

1171 - 7th Street
Des Moines, IA 50314
p: 1.877.811.7526
www.ppheartland.org

September 11, 2015

Diana Meyer, RN BSN – Program Manager
Office of Acute Care Facilities
DHHS Public Health – Licensure Unit
PO Box 94986
Lincoln, NE 68509

Dear Ms. Meyer,

Thank you for your recent review of our practices in our Omaha and Lincoln health centers. This letter is to address the finding of noncompliance regarding the statistical reporting requirements of our abortion patients, "Report of Induced Abortion" that is due to the state within 15 days of the end of the calendar month in which the abortion was performed. The following corrective action has been put in place:

- Reviewed requirements with management staff at both health centers.
- The manager is ultimately responsible for ensuring this task is completed timely, she may delegate the task to a staff person, but will be held accountable to see that it is completed.
- A calendar appointment has been placed on both center manager's calendars on the 8th of the month to remind staff that the reports are coming due.
- For the next 6 months, the regional director will confirm that the statistical report has been submitted timely.

Please let me know if you need additional information.

JWUlrick

Jennifer Warren Ulrick
Director of Health Services
Planned Parenthood of the Heartland

dw 9/15/15

Nebraska DHHS Licensure Unit

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HC056	A. BUILDING: _____ B. WING _____	08/21/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF THE HEARTLANI	3105 NORTH 93RD STREET OMAHA, NE 68134

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
G 020	7-006.01 Licensure Responsibilities The licensee of each health clinic must assume the responsibility for the total operation of the facility. The licensee responsibilities include: 1. Monitoring policies to assure the appropriate administration and management of the health clinic; 2. Maintaining the health clinic ' s compliance with all applicable state statutes and relevant rules and regulations; 3. Providing quality care and treatment to patients whether care and treatment are furnished by health clinic staff or through a contract with the health clinic; 4. Periodically reviewing reports and recommendations regarding the Quality Assurance/Performance Improvement program and implementing programs and policies to maintain and improve the quality of patient care and treatment; 5. Maintaining written minutes of meetings and actions; 6. Designating an administrator who is responsible for the day to day management of the health clinic and defining the duties and responsibilities of the administrator in writing; 7. Notifying the Department in writing within five working days when a vacancy in the administrator position occurs including who will be responsible for the position until another administrator is appointed; 8. Notifying the Department in writing within five working days when the vacancy is filled including effective date and name of person appointed administrator; and 9. Determining if emergency medical technician-intermediates or emergency medical technician-paramedics may perform activities within their scope of practice as either an employee or volunteer within the health clinic.	G 020		

Licensure Unit
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Nebraska DHHS Licensure Unit

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HC056	A. BUILDING: _____ B. WING _____	08/21/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF THE HEARTLANI	3105 NORTH 93RD STREET OMAHA, NE 68134

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
G 020	Continued From page 1 This Standard is not met as evidenced by: Surveyor: 15107 Based on staff interview; review of policy and procedures, review of certified mail receipts and DHHS statistical data; the HC (Health Clinic) failed to complete and/or submit the required Report of Induced Abortion form to the Nebraska Department of Health and Human Services (NDHHS) within 15 days after the reporting month for seven months out of seven months since January 1, 2015. Nebraska State Statute 28-343 requires the following: "The Department of Health and Human Services shall prescribe an abortion reporting form which shall be used for the reporting of every abortion performed in this state...The completed form shall be signed by the attending physician and sent to the department within fifteen days after each reporting month". Findings are: A. Review of the policy and procedure titled 'Statistical Reporting' (Revised 6/15) revealed the following: "The State of Nebraska requires that all abortions performed in the state be reported within 15 days of the end of the calendar month in which the abortion was performed. Nebraska Department of Health and Human services has provided us with a form to utilize for this purpose. The form is called Report of Induced Abortions. One form is filled out for each patient who has an abortion or spontaneous termination of pregnancy. The PP Heartland [Planned Parenthood] clinician who performed the abortion must sign the form. Forms are mailed monthly to the Vital Records Office by the 15th of the month."	G 020		

Nebraska DHHS Licensure Unit

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HC056	A. BUILDING: _____ B. WING _____	08/21/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF THE HEARTLANI	3105 NORTH 93RD STREET OMAHA, NE 68134

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
G 020	Continued From page 2 B. Interview with the Office Manager on 8/18/15 at 2:30 PM revealed the following: U.S. (United States) Postal Service Certified Mail receipts for the mailing of the State of Nebraska Report of Induced Abortion forms to Vital Statistics for reports for the months of December 2014 through May 2015. The Business Office Manager confirmed May was last completed report sent in and "I'm a little behind on that". Surveyor: 21534 C. A review of DHHS statistical data revealed the following information regarding the facility reporting: January 2015 - Report due to DHHS by February 15, 2015; the facility report was received on February 20, 2015. February 2015 - Report due to DHHS by March 15, 2015; the facility report was received on March 24, 2015. March 2015 - Report due to DHHS by April 15, 2015; the facility report was received on July 2, 2015. April 2015 - Report due to DHHS by May 15, 2015; the facility report was received on July 2, 2015. May 2015 - Report due to DHHS by June 15, 2015; the facility report was received on July 6, 2015. June 2015 - Report due to DHHS by July 15, 2015; As of August 25, 2015, no report had been received. July 2015 - Report due to DHHS by August 15, 2015. As of August 25, 2015, no report had been received.	G 020		

Department of Health & Human Services
DHHS
N E B R A S K A

Division of Public Health

State of Nebraska
Pete Ricketts, Governor

October 21, 2015

Mary Carhart
Administrator
Bellevue Health Center
1002 West Mission
Bellevue, NE 68005

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear Ms. Carhart:

On October 13, 2015 we conducted a revisit to verify that your facility had achieved and maintained compliance. Enclosed is the State Form: Revisit Report showing that your facility was found to be in compliance.

If you have any questions regarding this correspondence, please contact this office.

Sincerely,

Diana Meyer, RN BSN - Program Manager
Office of Acute Care Facilities
DHHS Public Health - Licensure Unit
P O Box 94986, Lincoln, NE 68509-4986
(402) 471-3484 FAX (402) 742-8319
Email: diana.meyer@nebraska.gov
DHHS.acutecarefacilities@nebraska.gov

DM/smm

Enclosures: State Form: Revisit Report

Department of Health & Human Services
DHHS
N E B R A S K A

Division of Public Health

State of Nebraska
Pete Ricketts, Governor

March 10, 2016

Jennifer Warren-Ulrick
Administrator
Planned Parenthood Of The Heartland
3105 North 93rd Street
Omaha, NE 68134

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear Ms. Warren-Ulrick:

On we conducted a review of paperwork for your revisit to verify that your facility had achieved and maintained compliance. Enclosed is the RevisitState Form showing that your facility was found to be in compliance.

Centers for Medicare and Medicaid Services (CMS) has been notified of the results of our finding that your facility is in compliance.

If you have any questions regarding this correspondence, please contact this office.

Sincerely,

Diana Meyer, RN BSN - Program Manager
Office of Acute Care Facilities
DHHS Public Health - Licensure Unit
P O Box 94986, Lincoln, NE 68509-4986
(402) 471-3484 FAX (402) 742-8319
Email: diana.meyer@nebraska.gov

DM/lc

Enclosures: CMS-2567B

Department of Health & Human Services
DHHS
N E B R A S K A

Division of Public Health

State of Nebraska
Pete Ricketts, Governor

July 5, 2016

Jennifer Warren-Ulrick
Administrator
Planned Parenthood Of The Heartland
5631 South 48th Street, Suite 100
Lincoln, NE 68516

IMPORTANT NOTICE - PLEASE READ CAREFULLY

Dear Ms. Warren-Ulrick:

On June 29, 2016 we conducted a review of paperwork for your revisit to verify that your facility had achieved and maintained compliance. Enclosed is the STATE FORM: Revisit Report showing that your facility was found to be in compliance.

If you have any questions regarding this correspondence, please contact this office.

Sincerely,

Diana Meyer, RN BSN - Program Manager
Office of Acute Care Facilities
DHHS Public Health - Licensure Unit
P O Box 94986, Lincoln, NE 68509-4986
(402) 471-3484 FAX (402) 742-8319
Email: diana.meyer@nebraska.gov

DM/smm

Enclosures: STATE FORM: Revisit Report